

CLAIMS

1. A self-contained, optical hand-held diagnostic device, the device comprising:

    a body having a pocket-sized form factor sized and shaped for engagement by a user's hand;

    a power supply disposed within said body;

    a display disposed integrally with said body;

    a holder configured for receiving reagent sample media therein, the sample media having a plurality of test areas disposed in spaced relation thereon, each of the test areas configured to react with a sample when disposed in contact with the sample and to change color according to an amount of a constituent or property in the sample;

    the holder sized and shaped for forming an indexed fit with the sample media;

    a micro-array of imagers disposed within said body;

    each of said imagers being superposed with a respective one of the test areas when the sample media is indexed within said holder;

    the imagers being configured to each capture an image of the test area respectively superposed therewith;

    a processor coupled to said imagers;

    said processor configured to analyze said images of said test areas;

    said processor configured to derive a diagnosis value from said analysis, and to generate an output corresponding thereto; and

    said display configured to receive and display said output;

    wherein said device is a unitary, self-contained, pocket-sized diagnostic tool.

2. The device of claim 1, wherein said diagnosis value comprises the amount of said constituent or property.
3. The device of claim 1, wherein said diagnosis value comprises a diagnosis of a condition.
4. The device of claim 1, wherein said sample media includes a test strip, and said test areas include test pads.
5. The device of claim 4, wherein said imagers collectively capture images of the entire test strip.
6. The device of claim 4, wherein each of the imagers is configured to capture an image of a discrete one of the test pads.
7. The device of claim 4, wherein the ratio of imagers to test pads is at least 0.5:1.
8. The device of claim 7, wherein the ratio of imagers to test pads is at least 1:1.
9. The device of claim 1, wherein said array of imagers comprises an array of image capture devices.
10. The device of claim 9, wherein said image capture devices comprise CCD devices.
11. The device of claim 9, wherein said image capture devices comprise CMOS devices.
12. The device of claim 9, wherein said array of imagers comprises a lens subsystem optically coupled thereto.

13. The device of claim 12, wherein said lens subsystem comprises an array of lenses.

14. The device of claim 13, wherein said array of lenses comprises a micro-lens array.

15. The device of claim 12, wherein said lens subsystem is configured to focus the images of the test pads onto respective ones of the image capture devices.

16. The device of claim 1, further comprising a light source configured to illuminate said sample media.

17. The device of claim 1, further comprising a memory device configured for storing diagnostic data.

18. The device of claim 17, comprising a memory device configured for storing calibration data.

19. The device of claim 17, comprising a memory device configured for storing the captured images.

20. The device of claim 1, further comprising a port configured for uploading and downloading data.

21. The device of claim 1, wherein said holder is hingedly coupled to said body.

22. The device of claim 1, wherein said sample media comprises a reagent cassette.

23. The device of claim 1, wherein said sample media comprises a microfluidic device.

24. The device of claim 1, comprising a sensor configured to detect when the sample media is indexed within said holder.
25. The device of claim 24, wherein said sensor comprises at least one of said imagers.
26. The device of claim 25, wherein said at least one imager is configured to detect when the sample media is indexed within said holder by capturing a desired image.
27. A self-contained, optical hand-held diagnostic device, the device comprising:
- a body having a pocket-sized form factor sized and shaped for engagement by a user's hand;
  - a power supply disposed within said body;
  - a display disposed integrally with said body;
  - a channel configured for receiving reagent test strip therein, the test strip having a plurality of test pads disposed in spaced relation thereon, each of the test pads configured to react with a sample when disposed in contact with the sample and to change color according to an amount of a constituent or property in the sample;
  - the channel sized and shaped for forming an indexed fit with the test strip;
  - a micro-array of imagers disposed within said body in fixed superposition with said channel;
  - each of said imagers being superposed with a respective one of the test pads when the test strip is indexed within said channel;
  - a light source configured to illuminate said test strip;

the imagers being configured to each capture an image of the test pad respectively superposed therewith;

a processor coupled to said imagers;

said processor configured to analyze said images of said test areas;

said processor configured to derive the amount of said constituent or property in the sample from said analysis, and to generate an output signal corresponding thereto; and

said display configured to receive said output signal and display said amount;

wherein said device is a unitary, self-contained, pocket-sized diagnostic tool.

28. A method for reading reagent sample media, the sample media having a plurality of test areas disposed in spaced relation thereon, each of the test areas configured to react with a sample when disposed in contact with the sample and to change color according to an amount of a constituent or property in the sample, the method comprising the steps of:

(a) receiving the sample media into a holder of a unitary, self-contained, optical hand-held diagnostic device having an integral power supply and display, the holder sized and shaped for forming an indexed fit with the sample media;

(b) with a micro-array of imagers disposed within said body, in which each imager is disposed in fixed superposition with a respective one of the indexed test areas, capturing images of said test areas;

(c) with an integral processor, analyzing said images of said test areas;

(d) deriving said amount of said constituent or property in said sample from said analysis;

(e) generating an output signal corresponding to said amount; and

(f) transmitting said output signal to the integral display.

29. The method of claim 28, wherein said sample media includes a test strip, and said test areas include test pads.

30. The method of claim 28, further comprising the step of calibrating the device.

31. The method of claim 30, wherein said calibrating comprises capturing an image of a calibration material of known reflectance.

32. The method of claim 31, wherein said deriving comprises:  
dividing the reflectance of said image of said test pad by the reflectance of said image of a calibration material;  
and

multiplying the result of said dividing by the known reflectance of the calibration material to generate a calibrated percent reflectance of the test pad.

33. The method of claim 32, wherein said deriving further comprises comparing the calibrated percent reflectance with known values of amounts of said constituent or

property at various predetermined percent reflectances, to determine the amount of said constituent or property at said calibrated percent reflectance.

34. The method of claim 32, comprising comparing the calibrated percent reflectance with known values stored within a look-up table.

35. The method of claim 33, wherein said deriving further comprises comparing said amount of said constituent or property to known diagnoses associated with various predetermined amounts of said constituent or property, to determine a diagnosis that corresponds to said amount of said constituent or property.

36. The method of claim 35, wherein said generating comprises generating a signal corresponding to said amount of constituent or property and to said diagnosis.

37. The method of claim 36 further comprising the step of displaying said amount of constituent or property and said diagnosis on said integral display.

38. The method of claim 28 further comprising the step of illuminating said test areas.